PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Nagy Adly Habib, et al.	
Serial No:	10/625,232	
Filed:	July 22, 2003	Group Art Unit: 3739
Title:	APPLICATOR FOR MICROWAVE RADIATION TREATMENT	Examiner: Aaron F. Roane
Docket No:	22413-14	

DECLARATION UNDER 37 C.F.R. §1.132

I, Gennady Victor Shevchenko, declare and state as follows:

1. I received a B.A. degree in physiology and Sport Medicine from The Moscow State Academy of Sport Medicine, Moscow, Russia in 1990. In 1994 I received a B.S. in Business Administration from Rutgers, The State University of New Jersey. In 1997 I received an Masters of Business Administration in Marketing from the Harvard Business School of The Moscow State University, Moscow, Russia.

2. I have over 15 years of experience in the marketing of surgical devices having worked for Ethicon, Inc., a Johnson & Johnson company, from 1993 to 1999; and United States Surgical, a division of Tyco International HealthCare, Inc., from 1999 to 2005; and RITA Medical Systems Inc. from 2005 to 2007 when RITA Medical Systems, Inc. was acquired by AngioDynamics, Inc. in February 2007.

3. I am currently employed by AngioDynamics, Inc. located in Queensbury, New York. AngioDynamics, Inc. is a leading provider of innovative electrosurgical medical devices used by surgeons, and other physicians, for the minimally invasive diagnosis and treatment of cancer and other diseases. AngioDynamics is the exclusive licensee of the above-referenced patent

application and the commercial embodiment of the device that performs the claimed method is known as the HABIB device. The HABIB device and its method of use are based on providing a device having an applicator coupled to a source of electromagnetic energy, wherein the applicator includes an array of needles. The array of needles is inserted into a desired depth of a volume of tissue to be treated, and electromagnetic energy is applied in three-dimensional fashion among the array of needles, that is between and across the needles, to heat the tissue and is then withdrawn. This procedure is repeated in a step-wise fashion along the length of a planned incision line. Finally, the surgeon makes an incision into the depth of tissue that has been heated and bloodlessly resects the tissue along the planned incision line. This three-dimensional application of energy is essential in allowing a surgeon to resect tissue from an organ resulting in bloodless surgery.

4. The method of using the commercial HABIB devices are accurately described by independent claims 1 and 3 of the above-referenced application. These claims are set forth below.

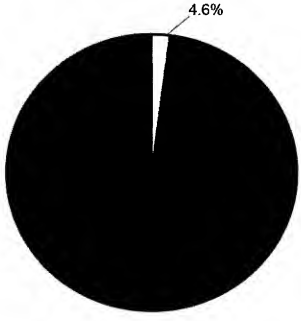
> 1. In the surgical treatment of a human or animal body, a method of controlling excessive bleeding, the method comprising:
> providing a device, the device comprising an applicator having at least one face and including an array of needles each needle including a tissue-piercing distal tip, said array of needles arranged on said at least one face of the applicator, said applicator structured to be operably coupled to a source of electromagnetic energy;
> positioning said array of needles so that said array of needles surround a volume of tissue to be treated, said array of needles serving to confine and transmit the electromagnetic energy field three-dimensionally;
> extending the tissue-piercing distal tips of said array of needles from said at least one face of the applicator into said volume of tissue to be treated at a point on a planned incision line;
> applying said electromagnetic energy three-dimensionally among said array of needles into the volume of the tissue to be treated at said point on the planned incision line;
> removing the tissue-piercing distal tips of said array of needles from the volume of tissue to be treated;
> advancing the applicator along the planned incision line in step-wise manner, extending the tissue-piercing distal tips of said array of needles into a volume of tissue to be treated along said planned incision line, and applying said electromagnetic energy three-dimensionally among said array of

needles into the volume of the tissue to be treated along said planned incision line until said microwave energy has been applied along the length of said incision line; and
bloodlessly resecting the tissue from the body.

3. A method of surgery on the human or animal body to control excessive bleeding, the method comprising:
(a) inserting a device into tissue or a part of an organ to be treated, the device comprising an applicator structured to be operably coupled to a source of electromagnetic energy, said applicator including an array of needles thereon, each needle having tissue-piercing means;
(b) positioning the tissue-piercing means of said array of needles into a desired depth of a volume of the tissue to be treated;
(c) applying the electromagnetic energy three-dimensionally among the array of needles into the desired depth of the volume of tissue to be treated to heat the tissue;
(d) advancing the tissue-piercing means of said array of needles along the length of a planned incision line; and
(e) making an incision into the desired depth of the volume of tissue which has been heated along said planned incision line; and
(f) bloodlessly resecting the tissue or part of organ from the body.

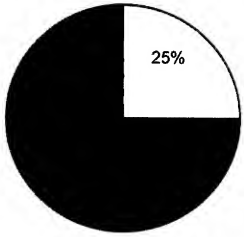
5. Since the commercial introduction in 2005 by RITA Medical sales and use of the HABIB devices have steadily increased. Below is a chart showing the estimated global market share of RITA Medical/AngioDynamics and its competitors in 2005.

2005 Estimated Share of Market Of HABIB Device Based on Gross Sales



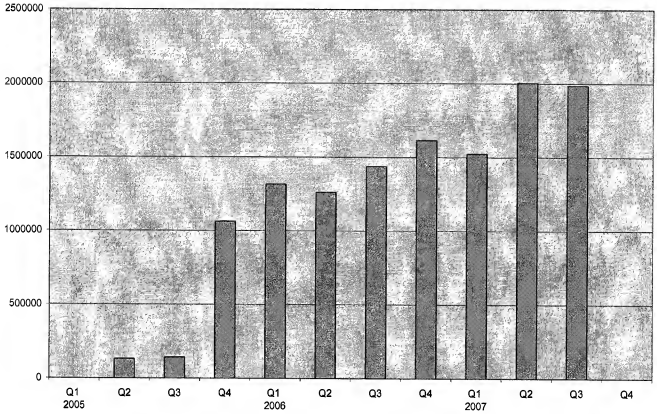
6. By 2007, in less than three years, the commercial success of the HABIB device is clear. As shown in the chart below, almost 25% of the market is now the HABIB device. This significant growth in market share of the HABIB device has been almost entirely at the expense of conventional surgical devices. In addition, this growth has occurred even though the cost of the HABIB device is typically higher than the cost of conventional systems. Thus, notwithstanding that the HABIB device is more expensive than conventional devices, there is no other device that is the functional equivalent of the HABIB device and no conventional device on the market today achieves what it achieves – superior clinical outcomes. Moreover, clinical studies conducted by investigators at Lahey Clinic in Burlington, Massachussetts; Celle General Hospital in Celle, Germany; and Charles University Medical School and Teaching Hospital, Czech Republic have shown that there are significant savings per procedure when the HABIB Device is used due to fewer clinical complications such as blood loss, transfusions, ICU stays; less operating room time; and the elimination of ancillary devices such as bioglues, medications, staplers, hemostatic powders and the like.

2007 Estimated Share of Market Of HABIB Device Based on Gross Sales



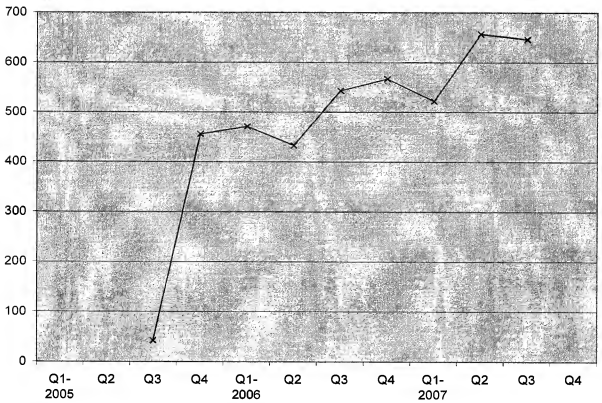
7. The commercial success of the HABIB device is also shown by the chart below, which shows gross sales in the United States only by quarter for 2005 (partial year), 2006, and 2007 (partial year through September). This chart shows approximately a ten-fold increase in U.S. gross sales over a relatively short period of time.

HABIB DEVICE GROSS SALES – U.S. ONLY



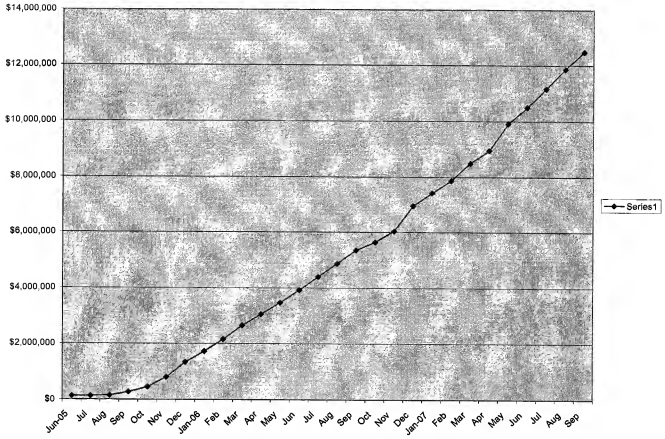
8. The commercial success of the HABIB device is also shown by the chart below, which shows unit sales in the U.S. only by quarter for partial year 2005, full calendar year 2006, and partial calendar year 2007 (through September). This chart shows more than a ten-fold increase in unit sales over less than a three-year period, a relatively short period of time.

HABIB DEVICE – UNIT SALES U.S. ONLY



9. The commercial success of the HABIB device is also shown by the chart below, which shows worldwide cumulative gross sales by quarter for partial year 2005, full calendar year 2006, and partial calendar year 2007. This chart shows the marked increase in worldwide gross sales on a cumulative basis over less than a three-year period, a relatively short period of time.

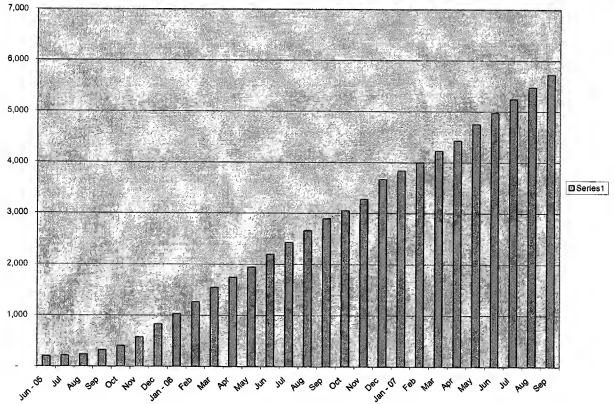
HABIB DEVICE WORLDWIDE CUMULATIVE GROSS SALES



10. The commercial success of the HABIB device is also shown by the chart below, which shows worldwide cumulative unit sales by quarter for partial year 2005, full calendar year 2006, and partial calendar year 2007. This chart shows the marked increase of worldwide unit sales on a cumulative basis over less than a three-year period.

HABIB DEVICE WORLDWIDE CUMULATIVE

UNIT SALES BY QUARTER



11. The commercial success of the HABIB device in the United States and its method of use is directly derived from the features claimed in claims 1 and 3 of the above-referenced application. The ability of the HABIB device to safely, effectively and reliably resect tissue to result in a bloodless resection is critical to its commercial success. This has permitted the HABIB device to penetrate 25% of the worldwide market in less than three years because of the advantages over conventional technologies. The commercial success of the HABIB device and its method of use flows directly from the functions and advantages disclosed in the above-referenced patent application, as specifically described in claims 1 and 3.

Under penalty of perjury, I declare that all statements made in this Declaration of my own knowledge are true and that all statement made on information and belief are believed to be true.

Date: November 6th, 2007

Gennady Victor Shevchenko